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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,924	12/23/2003	Sigfrid Schwarz	1815A	9015

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EXAMINER	
RAO, DEEPAK R	
ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 12/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/743,924	SCHWARZ ET AL.	
	Examiner	Art Unit	
	Deepak Rao	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/937,723.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 10-13 are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating atherosclerosis, does not reasonably provide enablement for a method of therapeutic treatment of men and women having all types of diseases of organs and tissues treatable by anti-oxidant compounds generally; or a method of treating brain injuries, spinal column injuries, shock, emphysema, ARDS, intoxication injuries, irradiation injuries, transplantation-related injuries, immune reactions, stroke, ischemia, CNS diseases, Alzheimer's type senile dementia, asthma or muscular dystrophy in men and women. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In evaluating the enablement question, several factors are to be considered. Note *In re Wands*, 8 USPQ2d 1400 and *Ex parte Forman*, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed. The determination that "undue experimentation" would have been needed to make and use the claimed invention is not a single, simple factual determination. Rather, it is a conclusion reached by weighing all the above noted factual considerations.

The scope of the claims is not adequately enabled solely based on the antioxidative activity of the compounds provided in the specification. First, the specification does not provide any test procedures or assays to determine the antioxidant activity of the compounds. Further, the specification does not contain any disclosure regarding how this antioxidative activity correlates to the treatment of all types of diseases associated with antioxidant compounds. The claim language includes diseases that are known and those that are yet to be discovered (see e.g., diseases of organs and tissues treatable by anti-oxidant compounds), for which there is no enablement. The instant claims cover brain injuries, spinal column injuries, intoxication injuries, irradiation injuries, transplantation-related injuries, immune reactions, CNS diseases, etc. that are known to exist and those that may be discovered in the future, for which there is no enablement provided. The use disclosed in the specification is as pharmaceutical therapeutic agents useful to treat diseases of organs and tissues treatable by anti-oxidant compounds.

Sparrow et al. (PubMed Abstract enclosed) in their reference indicate that 'antioxidants can have antiatherosclerotic activity', however, the state of the art is not indicative that compounds having antioxidant activity are useful in treating all types of diseases such as brain injuries, spinal column injuries, shock, emphysema, ARDS, intoxication injuries, irradiation injuries, transplantation-related injuries, immune reactions, stroke, ischemia, CNS diseases, Alzheimer's type senile dementia, asthma or muscular dystrophy. Parthasarathy et al. (ScienceDirect Abstract enclosed) in their article provide that "there are numerous contributing factors that need to be studied and understood before antioxidant therapy becomes an option for the treatment of cardiovascular diseases". Stocker (ScienceDirect Abstract enclosed) indicates

that "The results of major human randomized trials with antioxidants have, however, been disappointing, except for probucol, which consistently inhibits restenosis".

Further, the instant claims recite 'a method of treating brain injuries, spinal column injuries, stroke, ischemia, CNS diseases, Alzheimer's type senile dementia' - CNS diseases which includes "Neurodegenerative disorders" covers diverse disorders such as Alzheimer's disease, dementia, hereditary cerebellar ataxias, paraplegias, syringomyelia, phakomatoses, and much more, in fact, Layzer, Cecil Textbook of Medicine (article enclosed), states that "some degenerative diseases are difficult to classify because they involve multiple anatomic locations" (see page 2050). For example, Alzheimer's disease has traditionally been very difficult or impossible to prevent or even to treat effectively with chemotherapeutic agents. See e.g., the Cecil Textbook of Medicine, 20th edition (1996), Vol. 2, wherein it is stated that "[t]here is no cure for Alzheimer's disease, and no drug tried so far can alter the progress of the disease." (pg. 1994). Alzheimer's disease has no known cause and has been treated mostly by choline esterase inhibitors to prolong the activity of acetylcholine. Regarding antioxidant therapy in acute central nervous system injury, Gilgun-Sherki et al. (Pharmacological Reviews 2002) state that "Although some of the antioxidants showed efficiency in animal models, most of them did not show beneficial effect in clinical trials performed to date" (see page 281). The article concludes that "Better understanding of the underlying pathological mechanisms of acute CNS injury and improvement of the molecular design of antioxidants will open a full spectrum of possibilities for treatment of various types of injuries". Another state of the art reference, Prasad et al. (Journal of the American College of Nutrition, 2002) provides that "The etiology of Alzheimer's disease (AD) is not well understood" (see the abstract) and further "The effect of antioxidants in the

animal model of AD has not been investigated" (see page 513).

The instant claims recite 'a method of treating burns injuries'. Al-Kaisy et al. in their article regarding the antioxidant effect in the treatment of burns, indicate that "Further investigation is needed to explain the exact mechanism by which povidone-iodine exerts this antioxidant effect".

The instant claims recite 'a method of treating asthma'. Wood et al. (Eur. Respir. J. 2003) in their publication regarding the role of antioxidant therapy in airway inflammation and asthma, provide that "examination of airway biomarkers is critical to determine the potential for antioxidant supplementation to restore the oxidant/antioxidant imbalance" (see page 184).

The instant claims also include 'a method of treating muscular dystrophy' – Muscular dystrophies are a group of genetic and hereditary muscle disease. Duchenne MD is the most common form of muscular dystrophy affecting children, and myotonic muscular dystrophy is the most common form affecting adults. Diagnosis is usually established by muscle biopsy, elevated serum CK levels and electromyography examination, which is consistent with myogenic involvement. Some types of muscular dystrophy may present with additional cardiac disease, intellectual deterioration and infertility. There is no known cure for muscular dystrophy and there is no specific treatment for any of the forms of muscular dystrophy.

The instant claim recites diseases such as emphysema, acute respiratory distress syndrome, intoxication injuries, irradiation injuries, burn injuries, transplantation-related immune reactions, muscular dysrtophy, etc. for which applicant does not provide any nexus between these diseases and the disclosed antioxidant activity for the compounds. Further, there is no reasonable basis for assuming that the myriad of compounds embraced by the claims will all

share the same physiological properties since they are so structurally dissimilar as to be chemically non-equivalent and there is no basis in the prior art for assuming the same. Note *In re Surrey*, 151 USPQ 724 regarding sufficiency of disclosure for a Markush group.

Applicants have not provided any competent evidence or disclosed tests that are highly predictive for the pharmaceutical use of the instant compounds. Pharmacological activity in general is a very unpredictable area. Note that in cases involving physiological activity such as the instant case, "the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved". See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

The diagnosis of each of the disease is generally suggested by medical history and reports of endoscopy, cytology, X-ray, biopsy, etc. depending on the symptoms, signs and complications, which is essential to establish the dosage regimen for appropriate treatment or prevention. The disclosure does not provide any guidance towards the dosage regimen required to facilitate the treatment and/or inhibition of the claimed disorders, nor indicate competent technical references in the appropriate methods.

(Only a few of the claimed diseases are discussed here to make the point of an insufficient disclosure, it does not definitely mean that the other diseases meet the enablement requirements).

Thus, factors such as "sufficient working examples", "the level of skill in the art" and "predictability", etc. have been demonstrated to be sufficiently lacking in the use of the invention. In view of the breadth of the claim, the chemical nature of the invention, the unpredictability of ligand-receptor interactions in general, and the lack of working examples

regarding the activity of the claimed compounds, one having ordinary skill in the art would have to undergo an undue amount of experimentation to use the invention commensurate in scope with the claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Deepak Rao
Primary Examiner
Art Unit 1624

December 8, 2005